TESTIMONY

OF

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FDA OVERSIGHT PART I: THE INFANT FORMULA SHORTAGE

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Introduction

Chair McClain, Ranking Member Porter, and members of the Subcommittee, thank you for inviting me here today to testify before you and, more importantly, for your interest in better understanding what happened, so we can prevent an infant formula crisis of this nature from ever happening again.

Our bosses, the American people, and especially the most vulnerable of consumers – infants – deserve that from us, so I thank you for scheduling and conducting this hearing.

Background

In late February of 2022, already amid unprecedented supply chain challenges brought upon by the pandemic, our nation's parents and caregivers learned of a very large recall affecting trusted household brands of powdered infant formula (PIF) products, such as Similac, Alimentum, and EleCare manufactured in a facility located in Sturgis, Michigan. The company that produced these products, Abbott Nutrition (AN), voluntarily recalled these products after learning of multiple cases of infant illnesses caused by a rare and often fatal microorganism, called *Cronobacrer sakazakii*, which is often associated with PIF. Several confirmed cases of ill infants indicated that all had consumed PIF produced in AN's Sturgis facility. The illnesses, along with conditions detected at that facility during a FDA inspection, such as insanitary conditions, an environment contaminated with multiple strains of *Cronobacter sakazakii*, and critical equipment in disrepair, led AN to execute a voluntary recall on February 17, 2022. All in all, there were four infant illnesses of *Cronobacter sakazakki* linked this incident and, tragically, 2 of them resulted in death.

My Reason for Being Here Today

It has been over a year since this incident began. There has already been a Congressional oversight hearing held by a House Subcommittee on Oversight and Investigations in May of 2022. The FDA issued its own version of what transpired in a report in September of 2022 titled, FDA Evaluation of Infant Formula Response. And there has been extensive media coverage of the incident.

Yet, despite these actions, a clear and transparent understanding of what took place and the contributing factors that allowed it to occur - have remained elusive. It is most critical that we learn from this experience and take collective action as a nation to prevent something like this from ever happening again.

Consumers deserve better. And there is more that the industry and regulators can and MUST do.

Therefore, I come to you today without regard to partisan politics, but as a professional who has dedicated my life's work to protecting consumers, both in the public and private sectors. The

organism that caused these tragic illnesses, *Cronobacter*, does not recognize political parties, so as we search for solutions, neither should we.

I also come before you today with a balcony level view of what happened. While being made aware of the incident much too late, on February 10, 2022, a complete 4 months since the first of a series of illnesses and a whistle blower report were received by the agency, once I became aware, me and my team jumped into action and began coordinating daily meetings with executives of the various, decentralized offices and centers at the FDA involved with this issue. I also led the FDA's Incident Management Group (IMG) for the infant formula response, subsequent to the recall taking place.

What Follows

For the remainder of this testimony, my intent is to lay out the critical elements or factors that allowed this crisis to occur. My intent is to do that in a fact-finding – rather than a fault-finding – manner. And I hope to place a heavy emphasis in my testimony on the root cause and contributing factors that allowed it to happen, in hopes that it will allow us to focus on preventative solutions.

Why? Because, a year later, it is my view that the state of the infant formula industry today is not much different than it was then. The public health surveillance system for this pathogen remains insufficient, the necessary safeguards have not been advanced or strengthened at an adequate pace to prevent a re-occurrence or future illnesses, and the infant formula supply chain continues to lack resiliency. In other words, the nation remains one outbreak, tornado, flood, or cyber-attack away from finding itself in a similar place to that of February 17, 2022.

That place is a repeat scenario where parents hear of infants becoming severely ill due to *Cronobacter sakazakii*, finding shelves at their local grocery store empty for their desired infant formula products, and having to worry about the safety of what they are feeding their infants.

Below, I would like to spend the next few minutes walking you through my recollection of events, which I hope will paint a picture of why I am focused on these key areas.

Inadequate Public Health Surveillance for Illnesses caused by *Cronobacter sakazakii*

In 2011, Congress passed the Food Safety Modernization Act, known as FSMA. Their mandate to the industry and FDA then is still true today. It's not enough to respond to illnesses, outbreaks, or recalls of food after they happen. We must do more to prevent them from happening in the first place.

Much of what we know about foodborne illnesses, their frequency, severity, the foods that serve as primary vehicles for transmission, as well as common routes of contamination, is a result of progress made possible by foodborne disease surveillance efforts. Foundational to improvements to the food safety system is a modern foodborne disease surveillance program. As stated by Dr Scharff and Dr Hedberg in the book Food Safety Economics, published by

Springer Scientific, "a foodborne illness surveillance system is designed to collect, analyze, and disseminate information about foodborne illnesses. Consequently, they help solve critical information problems faced by consumers, firms, and government agencies. By providing better information to the market, these surveillance systems create incentives (accountability) that leads to safer foods and better consumer awareness."

In this instance, the foodborne disease surveillance system for *Cronobacter sakazakii* failed us and it MUST be improved.

Unlike other foodborne illnesses, *Cronobacter sakazakii* infections are NOT a nationally notifiable condition and is not reportable in most states. According to the Centers for Diseases Control and Prevention (CDC), Minnesota and Michigan are the only states that require reporting and the CDC reports that they typically receive reports of only 2 to 4 *Cronobacter* infections in infants per year. That means that there are likely cases of severe infant illnesses and deaths, although presumably rare, occurring in the United States due to *Cronobacter* and that those cases remain anonymous, unreported, and invisible to most of the nation.

A study by the CDC in 2014, published in the Journal of Emerging Infectious Diseases, titled Incidence of *Cronobacter* spp. Infections, United States, 2003–2009, estimated that the incidence of *Cronobacter sakazakii* among infants (zero to one year of age) was 0.49 per 100,000 population.

As illustration, for the incidence of another pathogen that is of low frequency but high severity, *Listeria monocytogenes*, the CDC estimates that there are 0.31 laboratory-diagnosed, domestically acquired infections per 100,000 population. This incidence rate is lower than that of *Cronobacter* among infants, the most vulnerable of consumers, yet *Listeria* is a reportable disease, but *Cronobacter* is not. It is only through reporting, and utilization of tools such as whole genome sequencing (WGS) of the isolates of *Listeria monocytogenes* detected that we have advanced what we know about Listeriosis. Because of that, today, we now know that many of the cases of Listeriosis that were once assumed to be isolated or sporadic, are not isolated at all. Increasingly, these cases are linked to a common food vehicle, allowing implicated foods to be taken off the market quicker, preventing additional illnesses, and outbreaks from getting larger. This, in turn, is enhancing our ability to create strategies to strengthen future prevention.

Lastly, in regard to making *Cronobacter sakazakii* a nationally notifiable condition, you have probably heard that this is not something the CDC, nor FDA can do on their own. There is a process through a body called the Council of State and Territorial Epidemiologists (CSTE) that meets annually to deliberate and vote on position statements and changes to national policy on notifiable conditions. This is a complicated process that is hard to explain to concerned parents, consumer groups, or public health advocates that wanted a change in notification policy to happen immediately after this issue was recognized. The CSTE is scheduled to meet in June of this year and I'm grateful that the FDA has been working to get this issue on the agenda. We

MUST change this and make *Cronobacter* a nationally notifiable condition just like Salmonella, E. coli O157, and Listeria.

Early Signal Detection and the Need for Rapid Response

As previously reported, the FDA began receiving a series of reports or complaints of infants who had been confirmed to have been infected with *Cronobacter sakazakii*, all who had also consumed infant formula products produced from a single manufacturing plant located in Sturgis, Michigan.

In addition, on October 26, 2022, the agency received a Whistle Blower complaint, submitted to various FDA personnel through various means (hard copies via Fed X, as well as electronic copies submitted via email).

In summary:

- The first report of an infant ill with C. sakazakii (which resulted in death) was reported to the FDA on Sept 20, 2021
- On October 26, the Agency received a Whistle Blower complaint alleging egregious conditions and practices at the Sturgis facility.
- The second report of an infant ill with C. sakazakii was reported to FDA on Dec 1, 2022
- The third report of an infant ill with C. sakazakii was reported to FDA on January 11, 2022, and
- The fourth report of an infant ill with *C. sakazakii* (which resulted in death) was reported to the FDA on Feb 18, 2022.

It should be noted that while the FDA conducted an inspection of AN's facility located in Sturgis on September 20, with the inspection lasting until September 24 of 2021, the inspectors on site were unaware of the complaint the agency had received of an infant illness due to *Cronobacter* on the same date, September 20, the day the inspection began. It would have been useful for investigators to have had that information on hand, as it could have potentially resulted in a different or more in-depth path of investigation.

While FDA did conduct notifications to the company of the illness reports as they came in and did slowly take steps to follow-up on the Whistle Blower complaint, it wasn't until January 31, 2022 (four months later) that the FDA began an official inspection of the AN's Sturgis facility and it wasn't until February 10, 2022 that I personally became aware of the series complaints, the whistle blower report, and the findings from FDA's January inspection that resulted in multiple environmental swabs being found positive for *Cronobacter sakazakii* in the facility.

Some have questioned if quicker action by the agency on some of the earlier signals could have avoided or lessened the magnitude of the crisis. While there is disagreement within FDA on this point, I believe most professionals experienced in crisis management would say the answer is yes. The literature is full of examples of organizations that either failed to piece together early signals or failed to heed early warnings that eventually allowed a crisis to grow worse,

rather than being contained. I believe that the literature of the future will also conclude that this incident is a sad example of how FDA's siloed organizational structure and culture impeded rapid critical problem identification, communication, and response.

Taking Whistleblower Complaints Seriously

In the Congressional hearing last spring, there was a lot of discussion about the whistleblower letters addressed to Drs. Woodcock, Mayne, and McMeekin being lost in the various FDA mailrooms for months. But what also concerns me greatly is the fact that the 30-plus page complaint was also sent by email to staff in the Office of Regulatory Affairs and CFSAN, but the concerns were not handled with the appropriate sense of urgency. Given the concerns expressed and the vulnerability of infants, this should have been elevated to leadership immediately. As Deputy Commissioner for Food Policy and Response, I was not sent the October 26, 2022 whistle blower complaint, and I did not get an opportunity to see the complaint until I was made aware of the incident in February 2022.

I would argue that FDA's structure and culture exacerbated these delays. With siloed groups in the FDA's decentralized Foods Program, it is impossible for leaders, even leaders like me that had titles that might indicate otherwise, to have clear line of sight on what was happening or to set processes in place to help catch these critical public health concerns. The current structure results in regular communication breakdowns, and results in the potential for food safety concerns to fall through the cracks altogether.

Eventually, the informant was interviewed by FDA personnel on December 22, approximately 2 months after the letter was received. While the concern over why it took so long to interview the informant is valid, as well as who were the individuals that received the letters, there is one significant conclusion that was not mentioned in the timeline and that did not come up during the initial hearing last spring. Upon completion of the interview with the confidential informant along with their lawyer present, the FDA investigators concluded that the complaint was "too vague" and did not warrant follow-up. Having read the letter myself and the very specific allegations of falsification of records, attempting to deceive federal relators, and more, it's hard for me to agree with outcome of the investigators' determination and, this too, could have played a role in delaying a greater sense of urgency by agency personnel aware at the time of the matter.

Again, FDA's future structure needs to be one in which the leader of the Foods Program can have clear line-of-sight on issues such as these and to take steps to ensure that the culture at FDA is one in which investigators recognize the need to take rapid action to follow-up on allegations like these. To accomplish this, FDA will need to empower a food safety leader with accountability for not just the Foods Center, but also the field inspectional resources in the Office of Regulatory Affairs.

The Weight of the Evidence Against Abbott

The inspection of the Abbott Sturgis facility initiated in January 2022 resulted in a number of findings that led to great concern for me and my colleagues and resulted in the large recall.

Abbott Nutrition and some others have suggested that their products were not the source of illnesses, because the genetic strains of *Cronobacter sakazakii* were never found in product, nor in the Sturgis facility. This information is misleading.

Thus, I would like to present a series of facts, regarding the weight-of-the-evidence of the problem at Sturgis that I was considering as we made the decision to request action by Abbott.

1. *Increased Reports of Cronobacter infections over a Short Period Time* – the FDA received 4 reports of confirmed *C. sakazakii* infections in infants over a short period of time, which is unusual, given that it is NOT a reportable illness in most of the U.S. Again, the CDC reports they have historically received 2 to 4 cases reported per year.
2. *Traceback* - all 4 infants that were infected had ingested PIF products manufactured at a single location (AN's Sturgis facility), which is significant. While AN certainly had a large market share, it was only one of 21 formula plants servicing the US market at that time.
3. *Microbiology* - FDA investigators readily found multiple environmental samples positive for *C. sakazakii* in the Sturgis plant in just a two-day period.
4. *Genetic Diversity* – five (5) different strains of C. sakazakii were detected using WGS of isolates in found the environment at the Sturgis facility, indicating contamination with multiple strains could occur.
5. *Lack of Environmental Control* - FDA's subject matter experts, well versed in infant formula production, described environmental conditions at the Sturgis facility as "out-of-control" and a potential source of recontamination.
6. *Old Spray Dryer with Large Cracks* – FDA investigators observed two sprayer dryers, one purchased in the 1960s, with large, unrepaired cracks, potentially serving as harborage points and sources of recontamination. This same scenario has been documented in the literature to have caused a PIF outbreak.
7. *Known Product Contamination* - FDA investigators learned that AN previously destroyed 2 batches of PIF contaminated with *Cronobacter* produced at Sturgis, even though it is well documented in the literature that low levels of sporadic contamination is unlikely to be detected by PIF sampling plans. Therefore, it is more likely than not that other batches of PIF produced in this plant were likely to have been contaminated with a variety *C. sakazakii* strains, which evaded end-product testing, and were released into commerce.
8. *Lax Standards* - events were recorded such as
    - contract workers moving from the roof to a production line in dirty boots, highlighting yet further avenues of potential contamination in the plant.
    - numerous water events were documented including water leaks, moisture, and condensation in dry powdered infant formula production areas.

- spray dryer inspections in August 2021 showed six instances of cracks and pits in the main chamber recorded for spray dryer #3 and six instances of cracks, pits, and damage in dryer #4

9. *PIF as a Vehicle of C. sakazakii* – contamination of PIF with *C. sakazakii* is well documented and has been the cause of small outbreaks and sporadic infections, sometimes with serious sequelae or death.
10. *Low Significance of Lack of WGS Match* - because *C. sakazakii* infections are not reportable in most states, it makes it more difficult to identify & link infections that may appear as sporadic in nature (i.e. Listeria). In this incident, four *C. sakazakii* infections were passively reported to FDA. Isolates were available for only two infants for WGS characterization. Having only two of four clinical cases characterized by WGS, and a scarce library of previous sequences, made it more difficult to compare limited infant infections with the multitude of strains (5) recovered from the firm, as well as previous documented human cases.

Based on the points summarized above, Abbott's Sturgis facility lacked adequate controls to prevent the contamination of powdered infant formula with *C. sakazakii*. There is also evidence that sporadic contamination of finished product actually did occur, and it is likely that other lots of PIF produced in this plant were contaminated with multiple *C. sakazakii* strains over time, which evaded end-product testing, were released into commerce, and consumed by infants.

Lastly, and in summary, the factors presented above supported a conclusion that PIF made at Abbott's Sturgis plant was produced under insanitary conditions and a likely source of ongoing, sporadic contamination of PIF with multiple strains *C. sakazakii* over time, notwithstanding a lack of a match by WGS between the plant's environment and/or finished product and two clinical isolates.

Need for Strengthening Preventive Controls within the Infant Formula Industry (Modern Facilities, Sanitary Design, Environment Monitoring, & Enhanced Verification)

A key lesson learned for me is that we need to update infant formula policies to strengthen prevention. While the conditions at the Sturgis plant were egregious, the Sturgis plant is not the only plant that has experienced problems with *Cronobacter*. As you may have seen in the news, there have been multiple recalls recently associated with the potential for *Cronobacter* at other facilities. We need to incorporate the lessons learned from recent events and update FDA's infant formula rule. One key example is our current testing regulations. Using the current testing requirements, the chances of detecting *Cronobacter* are much smaller than they should be. These standards need to be updated so that firms have a greater chance of detecting contamination events.

We also need to work more with industry to ensure production facilities are state of the art. In 2023, we should no longer be producing food for infants using equipment that is showing its age and increasing the risk of potential problems. Some of the equipment still being used in

some of the biggest production facilities today was installed before I was born. Back then, we knew far less than we do now.

Fulfilling Our Public Health Mission – Protecting Infants

From the time I first learned of the incident, on February 10, 2022 to the time it took Abbott Nutrition to conduct a voluntary recall to protect infants, it was 7 days. Seven days contrasted to the 4 months of time in which the series of events unfolded.

Beginning on February 11, 2022, as Deputy Commissioner of the Office for Food Policy and Response, I begin a series of daily meetings, sometimes more than once a day, with all Food Program principles and offices to include ORA, CFSAN, Legal, and Media Relations to coordinate activities and to work as one FDA Foods Program Team.

I wish that the communications silos had not existed and that I would have been notified earlier, so I could have initiated these steps sooner. I also believe that had we been able to initiate these steps and act sooner, the recall may have been smaller in size.

Addressing the Impact of the Recall

My Office initiated a prompt and escalated level of communication that informed major parts of the United States Government (USG) including the USDA and White House, of the evolving incident and its likely effect on infant formula supply availability.

The series of actions taken at all levels of the USG were well summarized in the hearing testimony provided in May of 2022 and, in my view, those collective actions were quite heroic. Below is a recap of select and notable actions.

- Asking retailers to quickly place limits on the number of units that could be purchased.
- Meeting regularly with major infant formula manufacturers to better understand and maximize their capacity to increase production of various types of infant formulas and essential medical foods.
- The prompt acquisition of needed data and monitoring the status of the infant formula supply by using the Agency's 21 Forward food supply chain continuity system, combined with external data.
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Implementing a new process to temporarily exercise enforcement discretion, on a case-by-case basis, for certain requirements that apply to infant formula. These flexibilities allowed for a small volume of infant formula to augment existing and newly produced supplies.
- The Administration invoking the Defense Production Act, directing firms to prioritize and allocate the production of key infant formula inputs to help increase production and speed up supply chains.

- Launching Operation Fly Formula and coordinating with the Department of Health and Human Services and U.S. Department of Agriculture (USDA) to leverage Department of Defense contracts with commercial air cargo lines to pick up overseas infant formula that met U.S. health and safety standards, so it could get to store shelves faster.
- USDA offering state health commissioners flexibilities through WIC to determine products that may be substituted for recalled products, allowing families to purchase different container sizes and physical forms, and allowing purchase of noncontract brands, and waiving retailer minimum stocking requirements to allow formula to transfer to where it was most needed.
- Congress passing the Access to Baby Formula Act of 2022 to expand access to baby formulas for certain American families during the supply chain disruption.

The Recall's Effect on the Infant Formula Shortage and Additional Factors that Could Have Minimized Disruptions

Clearly, the overarching measure that could have prevented this crisis from happening in the first place was Abbott Nutrition's operating conditions, procedures, standard of care, and commitment to maintaining a strong food safety culture. Simply put, what was found at Abbott's Sturgis facility was unacceptable and Abbott Nutrition bears the primary responsibility for this crisis.

Also, as previously mentioned, earlier detection of signals by Abbott, public health officials, and/or regulators could have allowed this incident to unfold in a less catastrophic manner.

However, after the series of events were allowed to escalate and build upon each other, by the time February of 2022 came along, containment of this incident became much harder.

There were longstanding gaps in Federal action on supply chain monitoring and resiliency actions that both helped to create a situation in which a single plant going offline could have such a tremendous impact. It also made it hard to have the intelligence needed at our fingertips to inform decision-making.

Even before the recall on Feb 17, 2022, the United States was already facing infant formula supply chain stress. Thus, as evidence of this cascading situation unfolded, the FDA knew that it had to act to protect infants, but that with an impending large recall of infant formula by a major market player, it also had to do everything it could, along with other USG partners, to minimize disruptions and potential shortages.

Per FDA's own Regulatory Procedures Manual, in Chapter 7 titled Recall Procedures, it states that "ORA and the Center (in this case, CFSAN) will also determine whether the recall could cause a shortage of regulated products." However, the FDA's Food Program was ill equipped to do a proper analysis of the effects of the recall on supply availability, as the team at CFSAN responsible for infant formula products lacked the type of quantitative infant formula supply chain insights, data and analytical capabilities to conduct a more thorough analysis of the

potential impact, simulate scenario planning, nor an ability to quickly determine what measures could be taken to accelerate a recovery.

21 Forward – a Food Supply Chain Data Analytical Platform

Prior to 2020, the Foods Program had no data system in place to monitor key food supply chains. During the COVID-19 crisis, many in federal service, including myself, felt it was our duty to do all that we could to gain better, data driven insights into the structure, function, and resilience of food supply chains, so that we could continue to meet the needs of the American people. Food and agriculture was one of those critical infrastructures that had to stay in operation to serve the public, and those of us working on this recognized that food security (ensuring people have access to food) was a matter of national security. Thus, we quickly realized that to protect and harden FDA-regulated food assets against the risk of SARS-Cov-2 transmission among food workers, we would need better data, insights, and additional data sets. And, thus, the idea of 21 Forward was born.

In record time and on a shoestring budget, my team, in partnership with other offices and an outside vendor, built the 21 Forward System, a first of its kind food supply chain data analytical platform that could be used to increase resiliency of the high priority food supply chains against COVID-19 related disruptions. It was achieved by transposing several ideas, leveraging disparate, but relevant data sets, and combing them with different computational capabilities. The system was used to strengthen FDA-regulated food assets from COVID-19 disruptions, including infant formula plants. As the infant formula crisis unfolded, we built on this system and turned it into the data platform for the entire USG response.

What the cross-governmental team did to build this platform was amazing and is a shining example of the dedication of public servants who worked around the clock to make this happen. But really, we shouldn't have been building this on the fly – it should have been in place years ago.

FDA had not made these investments because historically, the Agency's food mission has centered around food safety and nutrition. Even as COVID created the biggest challenge to the food system in a hundred years, there was internal debate at the agency on whether there was really a role for the FDA in monitoring food supply chains.

Requests for funding to further develop the 21 Forward system were met with resistance by the previous Acting Commissioner and Director for the Center for Food Safety and Applied Nutrition. In fact, one very specific request in advance of the infant formula crisis was declined by Agency leadership, despite Congress giving the agency unprecedented levels of money in the way of a COVID supplement funding to develop such capabilities. In hindsight, this was a big miss that would have enabled the Agency to respond to the infant formula crisis in a quicker, more thorough, and data-driven manner.

It was particularly frustrating to me and my staff that our early work on 21 Forward more than a year before the Abbott recall had highlighted for us the concentration of infant formula manufacturing, and we wanted to build out the monitoring tools to get a better handle on critical supply chains like these. In interagency discussions, we were raising infant formula as a good case study to advance supply chain actions – we had the right initial insights, and we were trying to make the case for resources – the emergency just came before the USG was ready.

Having lived this experience, I am grateful that Congress has directed the Center for Food safety and Nutrition to establish an Office of Critical Foods and the necessary capabilities to monitor these critical foods for potential disruption. I urge you to ensure that this office builds the appropriate monitoring tools and I urge you to continue to clarify expectations for the roles this new office and other parts of the Federal Government as they pertain to supply chain monitoring and mitigation actions.

A Fragile and Inelastic Infant Formula Supply Chain

Lastly, one should wonder, how does the shutdown of 1 of 21 infant formula plants serving the U.S. market cause such a shortage and disruption. And what were the factors that led to the creation of such an inelastic and fragile infant formula supply chain system.

The reality is that the FDA has had minimal authorities and levers to affect the system, other than the safety and nutrition standards they create and their ability to approve new markets submissions in a quick manner. However, like most supply chains, financial implications, incentives, and disincentives play a huge role in ultimately influencing how supply chains evolve. Thus, I am grateful that Congress, through the Omnibus, has requested that an Infant Formula Supply Chain Resiliency report be completed and submitted to them for review.

It is critical that Congress look for ways to encourage competition and redundancy of manufacturing in this industry. FDA has a role to play with its infant formula policies, but FDA is not alone. American taxpayers pay for about half of the infant formula sold in the U.S. through the USDA-WIC program. I would argue that the sole-source state WIC contracts helped to create the current concentrated supply chains. But WIC may also provide unique opportunities to address the need for greater competition and redundancy going forward. Congress must stay laser-focused on the resiliency report and create a more holistic approach that will keep us from repeating a scenario in which a single facility is the only manufacturing site for specialty formulas, and there is no back-up production capacity. Congress must insist that critical foods like formula not be one outbreak, tornado, flood, or cyber-attack away from a scenario similar to that of Feb 17, 2022.

Recommendations

In closing, I would like to leave this subcommittee with a brief list of select recommendations.

1. It's time to make *Cronobacter sakazakii* a nationally notifiable disease.

2. We should conduct WGS on all isolates of Cronobacter whether they come from clinical, environmental, or food samples and enter those genomic sequences into the National Center for Biotechnology Information (NCBI) database.
3. The FDA must enhance its ability to detect signals of potential safety concerns with regulated products and act on them with a greater sense of urgency.
4. Congress should address the cultural, siloed, structural, and leadership issues in the FDA Food Program that contributed to a less than desirable response to this incident.
5. Demand that the Infant Formula Industry set higher standards of care for themselves that include more modernized productions facilities and equipment, stronger preventative controls, enhanced sanitary design, more aggressive environmental monitoring, and statistically strengthened verification procedures.
6. Strengthen regulatory requirements for infant formula manufacturers to include more robust sanitary design, environmental monitoring, a revaluation of sampling plans beyond N=30 for *Cronobacter*, and mandatory reporting of product positives to the FDA.
7. Re-evaluate the thoroughness and frequency of FDA inspections conducted at infant formula manufacturers.
8. Re-invent the process used by FDA and health officials to investigate confirmed reports of *Cronobacter sakazakii* linked to a particular infant formula product. Right now, the process used is unscientifically overweighted on testing a few cans, without knowledge to how closely where those cans were produced in relation to the consumed product and without emphasize on the lack of statistical significance to the test results.
9. Dramatically improve consumer and physician education on the appropriate use and handling of PIF in hospitals and homes, as well as recommendations to use alternative sterile, liquid formulations for at-risk and premature infants.
10. Support the development of more modern, data-driven Food Supply Chain Analytic Platforms, such as 21 Forward, as a tool to address food supply chain challenges using data-driven insights.
11. Complete an in-depth Analysis of the Structure and Resilience of the Infant Formula Supply Chain in the U.S. and implement policies that will promote competition, diversification, resiliency, redundancy, and every day low costs for consumers.

Conclusion

In closing, ensuring the safety and availability of an often sole-source of nutrition, such as infant formula, is a tremendous responsibility for the industry that makes them and for the agencies that regulate them. The infant illness and deaths due to *Cronobacter*, the Abbott Nutrition recall, and the cascading and devasting effects it had on infant formula availability in our country was a preventable tragedy. It is my hope that we transparently seek the lessons learned and take the necessary actions to prevent such a crisis from ever happening again. Clearly, there is more the industry and regulators can and MUST do.

I thank this subcommittee and its members for your interest and I look forward to answering any questions you may have.